510(k) Summary

Prepared:	April 26, 2013
Submitter:	Ingen Orthopedics, LLC 2650 US Highway 130 Cranbury, NJ 08512
Contact:	Perry A. Geremakis President, Chief Executive Officer Ingen Orthopedics, LLC P: 609/409-3316 F: 609/409-3317 E: pgeramakis@ingenortho.com
Proprietary Name:	SEVIIN Fracture Shoulder
Common Name:	Fracture Humeral Stem Shoulder Prosthesis
Classification Names:	21 CFR 888.3660: Shoulder joint metal/polymer semi-constrained cemented prosthesis; Class II 21 CFR 888.3690: Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis; Class II
Product Codes:	KWS, HSD
Substantially Equivalent Devices:	Genesis Total Shoulder Replacement, K043346, cleared Jan 31, 2005 DePuy Global Fx Humeral Stem, Global Advantage, K984541, cleared Jan 14, 1999. Exactech Equinoxe Platform Fracture Stem, K092900, cleared Jan 7, 2010. Ingen Seviin Reverse Shoulder, K120374, cleared July 9, 2012.

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Device Description:

The SEVIIN Fracture Shoulder is a hemi or total shoulder prosthesis designed for use in patients with acute fracture of the proximal humerus. The modularity of the system allows for the later conversion of a primary hemi-arthroplasty to a total shoulder. Additionally, the SEVIIN Fracture Shoulder can be used with the SEVIIN Reverse shoulder for relief of pain or significant disability associated with a grossly deficient or non-repairable rotator cuff joint if necessary.

The Fracture Humeral Stems are manufactured from Ti-6Al-4V titanium alloy conforming to ASTM F136 and have a corundum blasted proximal surface to enhance bone cement fixation. Lateral fins with suture holes are designed for soft tissue attachment. The device features an anatomical neck/shaft angle and a 6 degree taper to mate with humeral heads (hemi or total shoulder) or a humeral cup (reverse shoulder).
Five sizes of fracture stems are available: 8, 10, 12mm diameter x 120mm and 8 and 10mm diameter x 200mm with a polished and fluted distal stem.

The Fracture humeral stems can be used with the SEVIIN Total Shoulder Humeral Heads and Glenoids (K043346) in addition to SEVIIN Reverse Shoulder components (K120374).

Intended Use / Indications:

Hemi or Total Shoulder:

The SEVIIN Fracture Shoulder is intended for cemented use for a severely painful and/or disabled shoulder joint resulting from osteoarthritis, traumatic arthritis or rheumatoid arthritis. It is also intended for fracture dislocations of the proximal humerus where the articular surface is severely comminuted, separated from its blood supply or where the surgeon's experience indicates that alternative methods of treatment are unsatisfactory. The device can be used in other difficult clinical problems where shoulder arthrodesis or resection arthroplasty are not acceptable (e.g., revision of failed primary component). Hemi-shoulder replacement is also indicated for un-united humeral head fractures and avascular necrosis of the humeral head.

Reverse Shoulder:

The SEVIIN Fracture Shoulder is also indicated for fracture total shoulder arthroplasty (due

to acute fracture of the proximal humerus in combination with degenerative diseases of the glenohumeral joint) for the relief of pain and to improve function in patients with a massive and non-repairable rotator cuff tear.

The patient's joint must be anatomically and structurally suited to receive the selected implants and a functional deltoid muscle is necessary to use the device.

The SEVIIN Fracture Shoulder humeral stems are intended for cemented applications. The glenoid components are intended for cemented use (total shoulder arthroplasty) and the TPS coated metaglene component is intended for cementless use with the addition of screws for fixation (reverse arthroplasty).

Summary of Technologies/Substantial Equivalence:

The SEVIIN Fracture Shoulder is substantially equivalent to the predicate devices in regards to its intended use and indications, materials, size ranges, and design intent. Any noted differences do not raise new types of safety and effectiveness questions, nor are there new technological issues.

Non-Clinical Testing:

Substantial equivalence was based on a comparison of intended use, indications, materials, sizes and design. Non-clinical testing was not performed.

Clinical Testing:

Clinical testing was not necessary to demonstrate substantial equivalence of the SEVIIN Fracture Shoulder to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 28, 2013

Ingen Orthopedics, LLC
Mr. Perry A. Geremakis
President, Chief Executive Officer
2650 US Highway 130
Cranbury, New Jersey 08512

Re: K131277
Trade/Device Name: SEVIIN Fracture Shoulder
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Codes: KWS, HSD, KWT
Dated: May 23, 2013
Received: May 30, 2013

Dear Mr. Geremakis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith

For

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131277

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Prescription Use ___X___ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices